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To: Commissioner of Patents  
 U.S. Patent and Trademark Office  
 Mail Stop Patent Ext.      Fax no.: **(571) 273-8300**

From: Tel. (202) 736-8000  
 Date: **16 January 2008**

Re: **U.S. Patent No. 7,314,619**Serial No.: **10/052,798**Confirmation No.: **4012**Filed: **November 2, 2001**First Inventor: **Camelia W. ADAMS**For: **APO-2 RECEPTOR**Group Art Unit: **1646**Examiner: **Eileen B. O'Hara**Attorney Ref. **22338-00904**  
**P1101R2D1****CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8**I CERTIFY THAT THE FOLLOWING DOCUMENTS ARE BEING TRANSMITTED TO THE USPTO AT  
 FAX NUMBER (571) 273-8300 THE DATE SHOWN:

**1. Request for Reconsideration of Patent Term Adjustment under  
 37 C.F.R. 1.705(d), including Attachments A and B (11 pages).**

Pamela J. Morris  
SIGNATUREPamela J. Morris  
PRINTED NAME1-16-08  
DATE

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent No. 7,314,619	Group Art Unit: 1646
Application Serial No.: 10/052,798	Examiner: Eileen B. O'Hara
Applicant: Camelia W. ADAMS	Attorney Docket No: 22338-00904 (P1101R2D1)
Filed: November 2, 2001	
Confirmation No.: 4012	
Title: APO-2 RECEPTOR	

Mail Stop: **Patent Ext**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**  
**UNDER 37 C.F.R. 1.705(d)**

Sir:

Applicant respectfully requests reconsideration of the Director's determination of Patent Term Adjustment (PTA) of U.S. Patent No. 7,314,619 (the '619 patent), issued on January 1, 2008. In particular, applicant requests a correction of the PTA by the **addition of 80 days** for delays attributable to the Patent and Trademark Office (PTO), resulting in a total PTA of **821 days**.

This request is filed within the two month period following the issue date of the patent and is therefore timely filed under 37 C.F.R. § 1.705(d). The Director is requested to charge applicant's Deposit Account No. 18-1260 the required fee of \$200.00 as specified in § 1.18(e). Any other fees that may be required may also be charged, and any overpayments credited, to the same account.

01/16/2008 ATRINH1 00000007 181260 10052798  
01 FC:1455 200.00 DA

U.S. Patent 7,314,619

Request for Reconsideration of Patent Term Adjustment under § 1.705(d)

**Facts**

1. U.S. Patent No. 7,314,619 issued from U.S. application serial no. 10/052,798 (the '798 application) on January 1, 2008. The '798 application was filed on November 2, 2001.
2. The '619 patent is not subject to a terminal disclaimer.
3. §1.702(a)(1) provides for patent term adjustment for failure of the PTO to mail a communication within 14 months of filing an application
4. §1.702(b) provides for patent term adjustment for failure of the PTO to issue a patent within three years after the date on which the application was filed.
5. §1.703 provides the manner by which the period of adjustment of patent term due to examination delay is assessed. Attachment A provides a copy of the PTO's determination of PTA for the '619 patent, as recorded in the PAIR system. This determination contains the same basis of the determination provided to applicant in the Issue Notification dated December 12, 2007.
6. The net PTA recorded in the PAIR system is **741 days**. This period reflects the PTO's determination that there were 1155 days of PTO delay, 414 days of applicant delay, and no three-year delay. The period of 741 days reflects the subtraction of 414 days from the 1155 days of PTO delay. The same net PTA is indicated on the face of the patent (copy also attached, Attachment B).
7. For the following reasons, the correct PTA period to which this application is entitled is **821 days**, which reflects the correct period of PTO delay of 1235 days, minus the period of Applicant delay of 414 days.
8. The PTO erred in calculating the period of PTO delay by incorrectly stating the duration of the delay period under §1.702(b).
9. The PTO has correctly determined that there was a period of PTO delay of **81 days** under §§ 1.702(a)(1) and 1.703(a)(1) due to the failure of the PTO to mail a communication within 14 months of filing. This period of 81 days is the period between January 2, 2004 and March 24, 2004.

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10. However, the PTO's determination that there were **1074 days** attributable to "PTA 36 Months" is not correct. The date that delay under § 1.702(b) began to accrue is November 3, 2004 (i.e., the day following the third anniversary of the filing date). Between that date and the date of the patent grant, January 1, 2008, **1154 days** elapsed.
11. §1.703(f) states that "[t]he term of patent entitled to adjustment under §1.702 and this section shall be adjusted for the sum of the periods calculated under (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704."
12. The "Three Years" delay under § 1.703(b) and §1.702(b) running from November 3, 2004 to January 1, 2008 (i.e., **1154 days**) and the examination delay under §1.703(a)(1) running from January 2, 2004 and March 24, 2004. (i.e. **81 days**) do not overlap. Accordingly, the total number of days this patent was delayed by PTO inaction is **1235 days**, not the 1155 days stated by the PTO.
13. The reductions under § 1.704 were correctly determined by the PTO, which are as follows:
  - **23 days** for failing to file a reply within 3 months to the Office communication mailed on March 24, 2003, for the interval between June 25, 2003 and July 17, 2003.
  - **89 days** for failing to file a reply within 3 months to the Office communication mailed on October 2, 2003, for the interval between January 3, 2004 and March 31, 2004.
  - **82 days** for filing an Information Disclosure Statement on June 21, 2004, after a reply had been filed on March 31, 2004 but before the June 28, 2004 Office Action was mailed.
  - **91 days** for failing to file a reply within 3 months to the Office communication mailed on June 28, 2004, for the interval between September 29, 2004 and December 28, 2004.

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- **92 days** for failing to file a reply within 3 months to the Office communication mailed on March 16, 2005, for the interval between June 17, 2005 and September 16, 2005.
- **37 days** for failing to file a reply within 3 months to the Office communication mailed on June 27, 2006, for the interval between September 28, 2006 and November 3, 2006.

The sum of these periods is **414 days**.

14. Applicant did not take any action that should be charged as a reduction in PTA under § 1.704 after the Office mailed its determination under § 1.705(d) with the Issue Notification. Thus, the PTO's calculations correctly reflect a total reduction under § 1.704 of **414 days**.
15. The difference between the "Three Years" delay plus the examination delay that does not overlap with the "Three Years" delay (i.e., **1235 days**) minus the period attributable to Applicant delay (i.e., **414 days**) is **821 days** (§ 1.703(f)).

### Discussion

§1.703(f) states that "[t]he term of patent entitled to adjustment under §1.702 and this section shall be adjusted for the sum of the periods calculated under (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704." This application is eligible for PTA corresponding to the sum of "Three Year" examination delay under § 1.702(b) and delay for failure to take action within specified times under §1.702(a) not overlapping with the delay period attributable to §§1.703(b) minus delay attributable by the applicant.

The period of "Three Years" delay is properly calculated as being the number of days within the complete interval of time specified at § 1.703(b). In this case, that interval is **1154 days**, not 1074 days as stated by the PTO.

In the prosecution of this patent, the period of delay under §§1.703(a)(1) and 1.703(b) do not overlap. The §1.703(a)(1) period of delay ran from January 2, 2004 to March 24, 2004, whereas the period of delay under §1.703(b) ran from November 3, 2004 to January 1, 2008.

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Request for Reconsideration of Patent Term Adjustment under § 1.705(d)

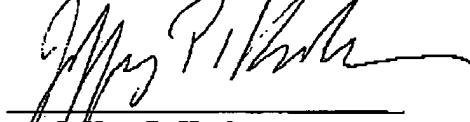
Thus, the correct period of examination delay is the sum of 1154 days for the period of delay under §1.703(b) plus the 81 days of the period of delay under §1.703(a)(1), resulting in a total delay of 1235 days, and not 1155 days as stated by the PTO.

§1.702(f) requires the period for adjustment of the term of this patent be reduced by the number of days applicant failed to engage in reasonable efforts to conclude examination of this application. The reductions in PTA under § 1.704(a) was correctly determined by the office to be 414 days. Therefore, the correct period of Patent Term Adjustment for the '619 patent is 821 days.

### Conclusion

In view of the foregoing, Applicant respectfully requests reconsideration of the PTO's determination of the period of patent term adjustment in the '619 patent, and correction of the patent to reflect a correct PTA period of 821 days.

Respectfully submitted,



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January 16, 2008

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A

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10/052,798	Inducing apoptosis using anti-Apo-2 antibodies	01-02-2008::10:42:01
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### Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/052,798

Filing or 371(c) Date:	11-02-2001	USPTO Delay (PTO) Delay (days):	1155
Issue Date of Patent:	01-01-2008	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	414
Post-Issue Petitions (days):	+0	Total PTA (days):	741
USPTO Adjustment(days):	+0	Explanation Of Calculations	

### Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
12-12-2007	PTA 36 Months	1074	
01-01-2008	Patent Issue Date Used in PTA Calculation		
12-04-2007	Dispatch to FDC	↑	
09-28-2007	Application Is Considered Ready for Issue	↑	
09-24-2007	Issue Fee Payment Verified	↑	
09-24-2007	Issue Fee Payment Received	↑	
09-24-2007	Receipt into Pubs	↑	
09-21-2007	Mail Miscellaneous Communication to Applicant	↑	
09-20-2007	Receipt into Pubs	↑	
09-20-2007	Sequence Forwarded to Pubs on Tape	↑	
09-18-2007	Miscellaneous Communication to Applicant - No Action Count	↑	
09-12-2007	Mail Examiner's Amendment	↑	
09-11-2007	Examiner's Amendment Communication	↑	
09-10-2007	Mail Notice of Allowance	↑	
09-07-2007	Document Verification	↑	
09-07-2007	Notice of Allowance Data Verification Completed	↑	
07-19-2007	Mail Examiner Interview Summary (PTOL - 413)	↑	
03-08-2007	Examiner Interview Summary Record (PTOL - 413)	↑	
07-06-2007	Mail Miscellaneous Communication to Applicant	↑	
07-06-2007	Mail Notice of Withdrawn Action	↑	
07-02-2007	Interference Communication: Initial Memo Disposal	↑	
07-02-2007	Letter Withdrawing / Vacating Office Action	↑	
06-28-2007	Miscellaneous Communication to Applicant - No Action Count	↑	
03-30-2007	Information Disclosure Statement considered	↑	
03-30-2007	Information Disclosure Statement (IDS) Filed	↑	
03-30-2007	Information Disclosure Statement (IDS) Filed	↑	
01-25-2007	Mail Final Rejection (PTOL - 326)	↑	
01-22-2007	Final Rejection	↑	
11-03-2006	Information Disclosure Statement considered	↑	
11-03-2006	Reference capture on IDS	↑	
11-03-2006	Information Disclosure Statement (IDS) Filed	↑	

11-03-2006	Information Disclosure Statement (IDS) Filed	↑
11-16-2006	Date Forwarded to Examiner	↑
11-03-2006	Response after Non-Final Action	37
11-03-2006	Request for Extension of Time - Granted	↑
06-27-2006	Mail Non-Final Rejection	↑
06-26-2006	Non-Final Rejection	↑
05-05-2006	Mail Examiner Interview Summary (PTOL - 413)	
05-01-2006	Examiner Interview Summary Record (PTOL - 413)	
04-24-2006	Date Forwarded to Examiner	
04-17-2006	Appeal Brief Filed	
04-17-2006	Request for Extension of Time - Granted	
03-21-2006	Date Forwarded to Examiner	
03-15-2006	Amendment/Argument after Notice of Appeal	
03-15-2006	Request for Extension of Time - Granted	
11-23-2005	Mail Advisory Action (PTOL - 303)	
11-21-2005	Advisory Action (PTOL-303)	
10-05-2005	Mail Advisory Action (PTOL - 303)	
10-03-2005	Advisory Action (PTOL-303)	
09-22-2005	Date Forwarded to Examiner	
09-16-2005	Amendment/Argument after Notice of Appeal	
09-16-2005	Notice of Appeal Filed	92
09-16-2005	Request for Extension of Time - Granted	↑
03-16-2005	Mail Final Rejection (PTOL - 326)	↑
03-14-2005	Final Rejection	
12-28-2004	Reference capture on IDS	
12-28-2004	Information Disclosure Statement (IDS) Filed	
12-28-2004	Information Disclosure Statement (IDS) Filed	
01-11-2005	Date Forwarded to Examiner	
12-28-2004	Response after Non-Final Action	91
12-28-2004	Request for Extension of Time - Granted	↑
01-07-2005	CRF Is Good Technically / Entered into Database	↑
12-28-2004	Workflow incoming amendment IFW	↑
06-21-2004	Reference capture on IDS	↑
06-21-2004	Information Disclosure Statement (IDS) Filed	82
06-21-2004	Information Disclosure Statement (IDS) Filed	
06-28-2004	Mail Non-Final Rejection	↑
06-26-2004	Non-Final Rejection	↑
04-13-2004	IFW TSS Processing by Tech Center Complete	↑
03-31-2004	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	↑
04-13-2004	Date Forwarded to Examiner	↑
03-31-2004	Response after Non-Final Action	89

03-31-2004	Request for Extension of Time - Granted	↑
03-31-2004	Workflow Incoming amendment IFW	↑
04-08-2004	CRF Is Flawed Technically / Not Entered into Database	↑
01-20-2004	Reference capture on IDS	↑
01-20-2004	Information Disclosure Statement (IDS) Filed	↑
01-20-2004	Information Disclosure Statement (IDS) Filed	↑
10-02-2003	Mail Non-Final Rejection	↑
10-01-2003	Non-Final Rejection	
07-29-2003	Date Forwarded to Examiner	
07-17-2003	Response to Election / Restriction Filed	23
07-17-2003	Request for Extension of Time - Granted	↑
03-24-2003	Mail Restriction Requirement	81
03-24-2003	Requirement for Restriction / Election	↑
07-22-2002	Information Disclosure Statement (IDS) Filed	↑
07-22-2002	Information Disclosure Statement (IDS) Filed	↑
02-22-2002	Information Disclosure Statement (IDS) Filed	↑
02-22-2002	Information Disclosure Statement (IDS) Filed	↑
04-17-2002	Preliminary Amendment	↑
11-02-2001	Preliminary Amendment	↑
05-23-2002	Case Docketed to Examiner in GAU	↑
05-14-2002	Application Dispatched from OIPE	↑
05-07-2002	Application Is Now Complete	↑
04-17-2002	Additional Application Filing Fees	↑
04-17-2002	Applicant has submitted new drawings to correct Corrected Papers problems	↑
04-17-2002	Applicant has submitted a new specification to correct Corrected Papers problems	↑
02-19-2002	Corrected Paper	↑
02-07-2002	CRF Is Good Technically / Entered into Database	↑
02-06-2002	IFW Scan & PACR Auto Security Review	↑
11-02-2001	CRF Disk Has Been Received by Preexam / Group / PCT	↑
11-02-2001	Initial Exam Team nn	↑

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**B**



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CENTRAL FAX CENTER(12) United States Patent  
Adams et al.(10) Patent No.: US 7,314,619 B2  
(45) Date of Patent: Jan. 1, 2008

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## (54) INDUCING APOPTOSIS USING ANTI-APO-2 ANTIBODIES

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 4,855,235 A 8/1989 Takahashi et al.  
 4,870,009 A 9/1989 Evans et al.  
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(73) Assignee: Genentech, Inc., South San Francisco, CA (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 741 days.

(21) Appl. No.: 10/052,798

(22) Filed: Nov. 2, 2001

## (65) Prior Publication Data

US 2002/0150985 A1 Oct. 17, 2002

2002/0048566 A1 4/2002 El-Dairy et al.  
 2002/0048785 A1 4/2002 Holzman  
 2002/0072091 A1 6/2002 Ni et al.  
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 2002/0161196 A1 10/2002 Alnemri  
 2003/0004313 A1 1/2003 Ashkenazi

## (51) Int. Cl.

A61K 39/00 (2006.01)  
C07K 16/28 (2006.01)

(Continued)

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DE 266710 4/1989  
 EP 036776 A2 9/1981  
 EP 073657 3/1983  
 EP 117058 A2 8/1984  
 EP 117060 A2 8/1984

(52) U.S. Cl. .... 424/133.1; 424/143.1;  
 424/141.1; 424/135.1; 424/142.1; 424/174.1;  
 424/192.1; 530/350; 530/387.1; 530/387.3;  
 530/387.9; 530/388.15; 530/388.22; 530/388.8;  
 514/2

(58) Field of Classification Search .... 514/2;  
 424/130.1, 135.1, 139.1, 141.1, 142.1, 143.1,  
 424/133.1, 134.1

(Continued)

## OTHER PUBLICATIONS

U.S. Appl. No. 08/815,255, filed Mar. 12, 1997.  
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 Adams et al., "Molecular cloning of mouse immunoglobulin heavy chain messenger ribonucleic acids coding for  $\mu$ ,  $\alpha$ ,  $\gamma 1$ ,  $\gamma 2a$ , and  $\gamma 3$  chains" *Biochemistry* 19:2711-2719 (1980).

(Continued)

Primary Examiner—Eileen B. O'Hara  
 (74) Attorney, Agent, or Firm—Sidley Austin LLP; Diane L. Marschang

## (57) ABSTRACT

Novel polypeptides, designated Apo-2, which are capable of modulating apoptosis are provided. Compositions including Apo-2 chimeras, nucleic acid encoding Apo-2, and antibodies to Apo-2 are also provided.

33 Claims, 20 Drawing Sheets